MAY - 9 2000

K001212

510(k) Summary

Submitted by:	Carter-Wallace, Inc. Carter Products Division P.O. Box 1001, Half Acre Road Cranbury, NJ 08512
Contact Person:	Stephen C. Kolakowsky Director, Regulatory Affairs (609) 655-6308
Date Prepared:	April 13, 2000
Proprietary Name:	TROJAN® EXTRA LARGE Latex Condom
Common Name:	Latex Condom, and Latex Condom with Spermicidal Lubricant
Classification Name:	Condom [21 CFR §884.5300], and Latex Condom with Spermicidal Lubricant [21 CFR §884.5310]
Predicate Device:	TROJAN-ENZ® Lubricated Latex Condom (Pre-1976 Amendments Device) TROJAN® MAGNUM® Larger Sized Latex Condom with Spermicidal Lubricant (#K895640)

Description of Device: The TROJAN® EXTRA LARGE Latex Condom is a sheath of natural rubber latex with silicone lubricant in one version and in the second version with silicone and the spermicide nonoxynol-9. The condom has a tapered-profile and a nipple end. The condom has a nominal length of 205 mm. The tapered profile shape starts at the closed end of the condom with an approximate flat-width of 64 mm and extents to the open end where the flat-width is approximately 57 mm. [Refer to ASTM D-3492-97 Specification for Rubber Contraceptives (Male Condoms).]

Intended Use of the Device: The 510(k)-subject condom has the same basic intended use as the predicate condom. The male condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs). The TROJAN® EXTRA LARGE Latex Condom is intended for men who feel that current regular and larger size condoms are too small.

Technological Characteristics: The 510(k)-subject device and the predicate devices are manufactured using the same formulation of natural rubber latex and condom production equipment and meet the same basic condom standard specifications of the ASTM Standard Specification for Rubber Contraceptives (Male Condoms) D3492, except the TROJAN® EXTRA LARGE Latex Condom is designed with wider flat width for the man who needs a larger sized condom.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Carter-Wallace, Inc.
Carter Products Division
P.O. Box 1001, Half Acre Road
Cranbury, New Jersey 08512

Re: K001212
TROJAN® EXTRA LARGE Male Latex Condom
Dated: April 13, 2000
Received: April 14, 2000
Regulatory Class: II
21 CFR §884.5300/Procode: 85 HIS
21 CFR §884.5310/Procode: 85 LTZ

Dear Mr. Kolakowsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

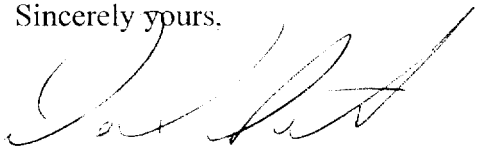
Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR 884.5300 and 884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in 801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, 801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, 801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in 801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number: (800) 638-2041 or (301) 443-6597, or at its Internet address: "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number: K001212

Device Name: TROJAN® EXTRA LARGE Latex Condom

Indications for Use: The TROJAN® EXTRA LARGE Latex Condom is intended for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs) by men who feel that current regular and larger size condoms are too small.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓

(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001212